K002323

Advanced UroScience, Inc. **Attachment 4**

JUL 31 2000

510(k) Summary

Submitter's Name, Address, and Date of Submission

Karen E. Peterson
Vice President of Regulatory, Clinical, & QA
Advanced UroScience, Inc.
1290 Hammond Road
St. Paul, MN 55110
Phone: 651-762-2146
Fax: 651-407-1975

Submitted: March 30, 2000

Device Name

Trade Name:	Advanced UroScience Injection needle
Classification:	II
Classification Name:	Endoscope and/or Accessories, 21 CFR 876.1500
Common/Usual Name:	Endoscopic Injection Needles

Predicate Device

Advanced UroScience Injection needle, [K982890].

Indication for Use

The Advanced UroScience Injection Needle is an accessory for currently marketed endoscopes to allow delivery of injectable materials into tissues during an endoscopic procedure.

Device Description

The Advanced UroScience Injection Needle consists of a stainless steel needle attached to a plastic luer lock hub where a standard syringe can be attached for injection of materials through the lumen of the needle into tissue. Multiple needle lengths and gauges are available to accommodate the length of the endoscope channel.

Technological Characteristics and Performance

The technological characteristics are the same as or equivalent to the predicate device. Biocompatibility and bench testing has demonstrated that the device is safe and effective and that its performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 1 2000

Ms. Karen E. Peterson
Vice President of Regulatory,
Clinical, and Quality Affairs
Advanced UroScience
1290 Hammond Road
St. Paul, MN 55110

Re: K002323
Advanced UroScience Injection Needle
Dated: June 26, 2000
Received: June 27, 2000
Regulatory Class: II
21 CFR §876.1500/Procode: 78 FBK

Dear Ms. Peterson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

Attachment 2

Indications for Use Statement

510(k) Number (if known) K002323

Device Name **Advanced UroScience Injection Needle**

Indications for Use

The Advanced UroScience Injection Needle is an accessory for currently marketed endoscopes to allow delivery of injectable materials into tissues during an endoscopic procedure.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109

(Optimal Format 1-2-96)

David A. Bigman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002323